A clinical comparison of pneumatic compression devices: The basis for selection

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Purpose: **The five pneumatic compression devices (PCDs) that are marketed provide mechanical protection from deep venous thrombosis (DVT). They differ with respect to patterns of compression and the length of the sleeve. Evidence linking differences to clinical outcomes is lacking. Our purpose was twofold: to evaluate each of the marketed PCDs with respect to effectiveness, compliance, and patient and nursing satisfaction and to determine whether there is a clinical basis for the selection of one device over another.**
Methods: **Each of the marketed devices was used exclusively for a 4-week period. Patients participated in an evaluation including venous duplex ultrasound scan, DVT risk assessment, and device evaluation. Vascular laboratory records were used to document DVT. Compliance was measured by meters installed on all pumps. A ranking matrix was stratified by compression pattern: rapid graduated sequential compression, graduated compression, and intermittent compression, and each device was rated by patients and nurses.**
Results: **The PCDs were used in 1350 cases with a DVT rate of 3.5% ranging from 2% to 9.8% depending on the method of compression. Patients with DVT were older (58 vs 54 years), had better compliance (67% vs 50%), and had more compression days (11 vs 7.2). When thigh-length sleeves were used, a greater proportion of DVT occurred in the proximal segments (71%) as compared with the number of proximal DVT when the calf-length devices were used (52%; *P* = .21). Devices W, X, and Y had comparable rates of DVT, which were lower than those for V and Z. Compression device Y, with calf and thigh sleeves, achieved the best overall ranking largely because of high scores for patient and nurse satisfaction.**
Conclusion: **Our data appear at odds with commonly held beliefs. We were unable to show a difference in DVT incidence based on the length of the device or the method of compression. Randomized studies are needed to confirm our findings and evaluate hypotheses derived from this study. (J Vasc Surg 2001;34:459-64.)**

Thromboembolism is a major source of morbidity and death among hospitalized patients, but it can be lowered substantially with an effective program of prophylaxis. The efficacy of pneumatic compression devices (PCDs) has been demonstrated in clinical studies.[1-3] Several types of devices are available, but there is insufficient evidence to determine selection of one over another. Purchasing decisions based on economic considerations, product name recognition, and unsupported claims of superiority are inappropriate. Selection criteria should include evidence that is based on clinical effectiveness: how the devices perform in the situation where they will be used.

Marketing claims are based on the type of compression (intermittent versus sequential) and the amount of tissue compressed (calf versus thigh), both of which affect blood flow volume and velocity.[4-6] Manufacturers cite differences in peak systolic velocity or volume flow as the basis for the effectiveness of the PCDs, but we are unaware of any convincing clinical studies that link prevention of DVT with these performance criteria. Furthermore, there are conflicting data regarding the presence of a fibrinolytic effect of compression.[7] Finally, there are no clinical trials to support the superiority of one product over another.[8,9] Nine months before the expiration of our Institutional PCD contract, investigators from the Section of Vascular Surgery were approached by the Materials Management and Purchasing Departments for assistance in identifying a PCD system for use at our academic medical center. We chose to perform an effectiveness study as opposed to a randomized clinical trial, because this design would allow us to evaluate the performance of PCDs as they are routinely used at this institution. Effectiveness research does not attempt to control variables as in a randomized clinical trial but to focus on clinical outcomes in a variety of situations.

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MATERIALS AND METHODS

We selected five evaluation criteria. In order of importance, these included the rate of DVT, compliance, patient acceptance, nursing acceptance, and finally, cost. A matrix was developed for this comparison (Table I). Each device was ranked on each criterion on a scale from 1 to 5 with 1 being the most desirable ranking.

A prebid conference was held for vendors interested in bidding for the PCD contract. The following requirements were identified:

1. Participation in a prospective study comparing clinical outcomes.
2. Provision of PCD pumps and sleeves for a 30-day period for which they would be reimbursed. (If a ven-

Table I. Matrix ranking of devices*

Device	*DVT*	*Compliance*	*Patient satisfaction*	*Nurse satisfaction*	*Total*
V	5	1	2	2	10
W	3	2	1	1	7
X	2	4†	3	3	12
Y	1	3	5	5	14
Z	4	4†	4	4	16

The lowest rank is the most favorable.
*The points 1 to 5 equal best to worst.
†Ties were given to the lowest ranking.

Table II. Devices are classified by the pattern of compression and the type of sleeves

Device	*Compression pattern*	*Sleeves*
V	Rapid gradient sequential	Calf
W	Intermittent compression	Foot, calf, thigh
X	Gradient sequential	Foot, calf, thigh
Y	Gradient sequential	Foot, calf, thigh
Z	Intermittent compression	Calf

dor did not have a full line of foot-, calf-, and thigh-length sleeves, the products currently used at our institution were substituted, but results from these patients would not be included.)

3. Addition of counters to the pumps for recording actual use.
4. Provision of inservice training and support to the nursing staff.

The bid from each manufacturer was submitted before initiation of the study.

After approval by the Institutional Review Board, all patients assigned PCD prophylaxis were asked to participate. Those who agreed completed a DVT risk factor assessment form (Appendix A, online only), completed a device evaluation form (Appendix B, online only), and underwent a venous duplex ultrasound scan before discharge. The criteria for a positive venous study included lack of vein compressibility and visualization of thrombus. Our laboratory protocol requires imaging both proximal and distal lower extremity segments including the iliac veins. The scans were obtained once PCD use dropped below 8 h/d. The diagnostic vascular laboratory and radiology records were reviewed to identify positive reports of deep venous thrombosis (DVT) or pulmonary embolism (PE) that may have occurred after the study screening. This review was continued for 60 days after the close of the study to identity recurrent events. When a patient's stay spanned the evaluation of two or more product lines, the initial device was used throughout. Data regarding additional methods of thromboembolism prophylaxis with standard heparin, low molecular weight heparin, and antiembolism stockings were obtained from the in-patient pharmacy and merged into the patient profile.

The counters on each pump were monitored every 1 to 2 days, and the final pump reading was obtained when the device was returned to Central Supply. A log of device use was maintained for each pump indicating the dates of service and the counter readings at initiation and conclusion. Materials Management provided a daily list of all pumps that were in use. At the conclusion of the study, clinical data were compared with records for PCD use maintained by Materials Management, and inconsistencies were resolved. One week before the end of each 30-day period, nursing personnel completed a device evaluation form (Appendix C, online only). The patient and nursing surveys were scored on a scale of 1 through 5. The individual responses were subtracted from the perfect response for each question. The differences were then totaled to obtain an evaluation score for each subject. An average score for each device was calculated, and these scores were ranked on a scale of 1 through 5 for inclusion in the matrix. Patients who did not agree to the risk assessment or ultrasound study still had PCD pump time monitored.

This was a prospective, observational, cohort study to determine the clinical effectiveness of currently marketed PCDs. Purchasing and Materials Management employees were masked to the clinical results of the study, whereas the Vascular Surgery investigators were masked to the economic factors. The primary objective was to identify the device with the best score on the ranking matrix. The analysis of the study data involved completion of the matrix and a stepwise decision process. If one device was clearly more effective, that device would be selected. If not, we would look at compliance, patient satisfaction, and nursing acceptance. Vendors whose final matrix totals were within 3 points of each other would then be rated on an economic basis. Secondary analyses were conducted to establish hypotheses for future investigation.

Data were entered into an Excel spread sheet (Microsoft, Redmond, Wash) and analyzed with SAS software (SAS Institute, Cary, NC). Most analyses were descriptive, in which the mean and SD for each variable were reported. Continuous data were analyzed with analysis of variance or *t* tests, whereas the likelihood ratio χ^2 test and the Fisher exact test were used for dichotomous data. Because we were attempting to generate hypotheses for future studies, a *P* value of .1 was used. Sensitivity analysis with various methods for determining the incidence of

Table III. Percentage of proximal DVT stratification

	Proximal	*Distal*	*Both*	*% Proximal*
By device				
V	4	6	2	50
W	5	6	3	57
X	5	3	0	63
Y	2	2	2	67
Z	4	3	1	63
By sleeve length				
Knee	11	15	5	52
Thigh	9	5	3	71

DVT was performed to determine whether it influenced the final matrix ranking (Appendix D, online only).

We have chosen to identify each device by the mechanism of action rather than by specific names of the manufacturers to avoid providing a commercial advantage. In addition, we have seen the ownership of a device move from one vendor to another and new devices using similar mechanisms enter the market. This should facilitate generalizability of the data. Table II lists the mechanism of action as described by the vendor and the alphabetical identification we assigned to each.

RESULTS

The five vendors attending the prebid conference chosen to participate in the study included Venodyne (Microtek Medical, Inc, Columbus, Miss), NuTech (KCI Company, San Antonio, Tex), Kendall (Kendall, Mansfield, Mass), Huntleigh (Huntleigh Healthcare, Eatontown, NJ), and Aircast (Aircast, Inc, Summit, NJ). Two of the vendors offered only a calf-length device, so the number of patients in groups V and Z was significantly less than that of the three vendors with complete lines. Patient enrollment took place between April and September 1999, during which 1350 in-patients were ordered PCDs by their attending physician and had them delivered. Consent for full participation was obtained from 473 patients. Duplex screening was completed for 243 patients, which identified 29 asymptomatic cases of DVT. Thirty patients from the study population who had symptoms of DVT underwent diagnostic scanning, which revealed an additional 19 cases of DVT. There was no diagnosed PE among the 1350 patients. A risk assessment was completed for 473 patients. At least two pump readings were available for 648 patients. The remaining patients were not admitted to the hospital after outpatient surgery or were admitted for less than 48 hours, which did not provide sufficient time to enroll them in the study. These patients were included in our review of the Vascular Laboratory and Radiology data for the diagnosis of thromboembolism.

Deep venous thrombosis. During this period 90 cases of DVT were diagnosed among in-patients, with 48 occurring in those using PCDs. There were no deaths associated with thromboembolism in this group. Table IV lists patient characteristics. On average, the groups differed with respect to the incidence of DVT, the number of days the pumps were in use, and the percentage of female patients.

We stratified our results first by the length of the compression sleeve and then by the absence or presence of DVT. We failed to identify a difference in patient characteristics associated with the sleeve length. The incidence of DVT was 3.6% among the 853 patients with calf-length devices and 3.4% among the 497 with thigh-length devices. Patients with DVT tended to be older by 4 years and were more likely to be male (54% vs 37%). They had more days of pump use (11 vs 7 days) and better compliance (16 vs 12 h/d).

The incidence of DVT ranged from 2% to 9.8% among the devices ($P = .003$). When stratified by sleeve length, the difference remained significant among the calf-length devices ($P = .001$) but not among the thigh-length sleeves ($P = .19$). This was probably due to a Type II error because there were fewer thigh-length devices used. It is possible that we have underestimated the incidence of asymptomatic DVT because we were unable to complete venous duplex studies for all patients who consented. However, by including all reports of symptomatic DVT or diagnosis of PE, we have captured all clinically important events. It was possible to calculate the DVT rate in several ways. We performed a sensitivity analysis using three different methods of calculating the incidence rates: the total number of DVT divided by the total number of patients, the total number of DVT divided by the total number scanned, and the total number of DVT divided by the number consented. Although the rankings differed slightly, the overall matrix ranking was insensitive to the method of calculation (Appendix D, online only).

We found that the use of pharmacologic prophylaxis was consistent across the five evaluation periods, ranging from 17% to 23% ($P = .45$) and should not have influenced the outcome. Of the 275 patients who received a second method of prophylaxis, 229 received heparin, 27 had stockings, and 19 had both heparin and stockings. Nineteen patients with additional prophylaxis had DVT, all in the heparin group. The use of additional prophylaxis, as well as the length of the PCD sleeve and the period of use, was managed by the attending physician because we were evaluating the devices as they were routinely used.

Table IV. Patient characteristics stratified by device type

Device	*Pump (d)**	*Age (y)*	*% DVT**	*Risk*	*Compliance*	*No. of patients*
V	10.6	53.6	9.8	3.9	12.9	124
W	7.2	54.2	3.2	4.2	13.6	432
X	6.6	54.8	2.5	4.1	11.1	372
Y	6.7	53.2	2.0	4.2	12.6	297
Z	8.8	55.7	6.4	3.9	10.5	125

* $P < .05$.

The locations of the DVT are summarized in Table II. The percentage of DVT that were proximal versus distal ranged from 50% to 67% depending on the vendor. When we stratified the data according to sleeve length, we found a higher incidence of proximal DVT among those with thigh-length (71%) versus calf-length (52%) sleeves ($P = .21$).

Compliance. Counters affixed to each pump were read every 1 to 2 days and at the time of their return to central supply. Compliance was rated as poor if the usage was less than 8 hours per reading, fair if it was between 8 and 16 hours, and good if it was more than 16 hours. A rating scale of 1, 1.5, or 2 was assigned to each level, respectively. The percentage of patients falling within each group for a particular device was multiplied by the rating and summed to determine the compliance score that ranged from 139 to 154 ($P > .05$). There was no association between the incidence of DVT and the percentage of patients falling into each level of compliance for either the calf- or thigh-length devices ($P = .15$ and $P = .58$, respectively).

Patient satisfaction. A total of 391 patients completed a seven-question survey about their experience with PCDs. The topics included comfort, mobility, sleep interference, and noise. They were to indicate whether they would use the device again and whether they would prefer a once-daily injection instead of using the device. There were statistically significant differences among the devices with respect to all the questions except willingness to use the device again. The level of significance ranged from a P value of .0001 to .01. See Appendix E (online only) for the details of the calculation. Vendor W had the highest level of acceptance, especially with respect to comfort and quietness; Vendor V closely followed. Patients consistently rated Vendor Y as the least desirable.

Nursing acceptance. Nurses completed an eight-question survey (Appendix C, online only). They answered questions about patient complaints, ease of application, frequency of alarms, interference with care, patient mobilization, and willingness to use the device. Between 81 and 133 nurses completed each survey, and the mean satisfaction scores ranged from 5 to 19, with 5 being the most desirable. Devices W and V were the most preferred systems. The nurses indicated a high number of patient complaints with Device Y and problems with application of the device and the number of alarms. The number of patient complaints and the ease of application were the two most important factors, with P values ranging from .0002 to .004. Interestingly, both patients and nurses ranked the devices in the same order.

Decision process. The completed matrix was reviewed (Table I). With respect to effectiveness, the analysis of variance indicated significant differences among the devices. V and Z had a higher incidence of DVT (9.8% and 6.5%) compared with W, X, or Y (3.2%, 2.5%, and 2%). The latter were very similar. V and Z were dropped from further consideration because of the importance we placed on effectiveness. Device W had the best scores for patient and nursing acceptance and the second ranking for compliance, resulting in the best overall ranking of 7. Device X was next at 12, whereas Device Y had a score of 14 because of poor acceptance scores. We therefore recommended device W. These data were provided to Purchasing and Materials Management for action. Happily, the bid submitted by Vendor W was also the lowest, making the decision straightforward. Vendor W offered the most desirable product at the best price.

DISCUSSION

This study includes both clinical and economic factors. It was conducted to ensure quality patient care at an attractive cost. The effectiveness trial methodology was adapted to allow us to answer our research question: Which device was the most cost-effective in this setting? The generalizability of our results to smaller community settings is questionable. This is a large academic medical center that attracts a patient population whose risk of DVT is high. We are also a high-volume user of PCDs. Nurses have heavy patient assignments, and we noticed early on that the compliance estimates were low, with most of the PCDs in use less than 12 h/d. Although this was a significant concern, we did not attempt to influence practice during the period of the study to avoid biasing the results.

There are several limitations to this study.

1. Patients were not randomized. Instead, each device was used exclusively for a 30-day period. There was no reason to believe that patient profiles or physician practices would differ from month to month. When we checked this assumption, we noticed that the number of days the pump was used was higher while evaluating devices V and Z, and we can not explain this finding. We also noted that the percentage of female patients was greater in these two groups. How this might have affected the outcome is unclear.

2. There was a reduction in the number of PCDs used during this 5-month period relative to the same period 1 year earlier and a reduction in the length of stay for postoperative patients so that fewer patients were enrolled.
3. The number completing the survey was lower than anticipated. It is possible that we only captured the opinion of those who had a very positive or negative experience, and this may have biased the results.
4. Many patients were discharged before undergoing the routine ultrasound venous duplex examination. This may have biased our estimates of the incidence of asymptomatic DVT. By following the Diagnostic Vascular Unit records, we were able to pick up any symptomatic DVT.

Despite the limitations, we think that this study allowed us to identify a brand of PCDs that provides excellent value to our patients and institution. It is effective, the patients and nurses find it acceptable, and the cost is reasonable.

Implementing product W meant that we changed from an intermittent sequential compression system to a simpler intermittent device. As a quality assurance measure we compared the incidence of DVT during a 6-month period before the trial with the incidence during the first 6 months of use and found no difference. There were 61 DVTs among the 11,943 admissions from April to September 1998 (0.51%) compared with 63 of 13,228 (0.47%) from April to September 2000. There were 90 diagnosed DVTs during the study period, but these included the asymptomatic DVT found during screening examinations.

Some of the findings from this study raise questions about commonly held beliefs. Many physicians think that full-length sleeves compress a greater volume of tissue and therefore provide a higher level of protection for patients at higher risk. Our data did not support this belief. The incidence of DVT was similar (3.4% vs 3.6%) among patients of similar age and risk of thromboembolism. It is also assumed that compliance is associated with effectiveness, yet we failed to find a significant association between the hours of use and the incidence of DVT. We have previously reported differences among the five devices with respect to peak systolic velocity, mean systolic velocity, and peak volume flow in normal volunteers (Society of Vascular Technology, Orlando, Fla, August 2000). When we compared these values with the incidence of DVT from the current study, we found that devices that achieved the greatest percent increase in peak systolic velocity also had the highest incidence of DVT. This is a clinically untested finding that requires further investigation, but it suggests a potential risk of increasing DVT from excessive tissue compression.[4]

Much is yet to be learned about the mechanisms by which PCDs prevent thromboembolism. As devices enter the market, the Food and Drug Administration grants 510(k) approval based on equivalence to predicate devices. They do not require clinical studies. As a result, there has been little effort to study the relative value of the various compression cycles and patterns. We found the evidence from this effectiveness study convincing and sufficient to support the selection of an intermittent compression device for use at our institution and our initial quality assurance procedures appear to support the validity of the process.

REFERENCES

1. Hartman JT, Pugh JL, Smith RD, Robertson WW, Yost RP, Janssen HF. Cyclic sequential compression of the lower limb in prevention of deep venous thrombosis. J Bone Joint Surg Am 1982;64A:1059-62.
2. Pidala M, Donovan D, Kepley R. A prospective study on intermittent pneumatic compression in the prevention of deep vein thrombosis in patients undergoing total hip or total knee replacement. Surg Gynecol Obstet 1992;175:47-51.
3. Woolson ST, Watt M. Intermittent pneumatic compression to prevent proximal deep venous thrombosis during and after total hip replacement. J Bone Joint Surg Am 1991;73-A:507-12.
4. Kamm R, Butcher R, Froelich J, Johnson M, Salzman E, Shapiro A, et al. Optimisation of indices of external pneumatic compression for prophylaxis against deep vein thrombosis: radionuclide gated imaging studies. Cardiovasc Res 1986;20:588-96.
5. Nicolaides AN, Fernandes JFE, Pollock AV. Intermittent sequential pneumatic compression of the legs in the prevention of venous stasis and postoperative deep venous thrombosis. Surgery 1980;87:69-76.
6. Vanek VW. Meta-analysis of effectiveness of intermittent pneumatic compression devices with a comparison of thigh-high to knee-high sleeves. Am Surg 1998;64:1050-8.
7. Christen Y, Wutschert R, Weimer D, De Moerloose P, Kruithof EKO, Bounameaux H. Effects of intermittent pneumatic compression on venous haemodynamics and fibrinolytic activity. Blood Coagul Fibrinolysis 1997;8:185-90.
8. Dai G, Gertler JP, Kamm RD. The effects of external compression on venous blood flow and tissue deformation in the lower leg. J Biomed Eng 1999;121:557-64.
9. Mittleman JS, Edwards WS, McDonald JB. Effectiveness of leg compression in preventing venous stasis. Am J Surg 1982;144:611-3.

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DISCUSSION

Dr Roger T. Gregory (Virginia Beach, Va). As usual Dr Greenfield's team from Michigan has evaluated an important area of venous disease. Mechanical devices are much more attractive than pharmacologic agents for DVT prophylaxis particularly in postoperative patients. We have used these devices in Norfolk for over 10 years and anecdotically have never seen a case of DVT when they were used. Routine ultrasound scanning was not used in all our patients, however. At least no clinically significant case of DVT was encountered.

Which is the best of the multiple devices available forms the basis for the current study. I have three questions for you:

1. Shouldn't venous dynamics and the instance of DVT be related?
2. Why are there several areas of disagreement between your study and previous reports on the same subject?
3. And finally a practical question: Your data suggest that mechanical devices do not provide an additive form of protection when used with pharmacologic prophylaxis. Why not?

I enjoyed your paper and hope this is an early report with more definitive conclusions to follow. Thank you.

Ms Mary Proctor. Thank you very much. We were interested in looking primarily at the effectiveness of the devices but also at understanding the underlying mechanism of action for the effectiveness of the device, and so in addition to the study of hospitalized patients, we conducted an evaluation of performance in normal volunteers to look at the hemodynamic effects of the devices. This raised more problems in our minds than we had initially because the finding indicated that devices with higher peak velocity were the devices that had a higher incidence of DVT among patients. This appears to fly in the face of common wisdom, which says that if you compress at a higher rate you clear the vein more rapidly and more effectively. We are continuing to evaluate this effect.

Our data differ from others in three respects. One, the number of subjects was larger. Two, it was not a randomized study. And three, we compared all of the available devices rather than just one device relative to another or one device relative to another prophylactic method.

Finally, I did not have time in the presentation, but we did look at additional prophylaxis in these patients to make sure that the groups were equivalent, which they were. We found a group of patients who had the combined use of mechanical and pharmacologic protection who still went on to develop DVT. It is this group of patients who will be the target of our future research.

Dr G. Patrick Clagett (Dallas, Tex). I congratulate you; these data are sorely needed. What was the population of patients that you studied? Were they general surgery patients, trauma patients, and orthopedic patients? The risk of DVT and your end point event rate are going to be much higher depending on the population you choose. I would suggest that if you had patients, such as stroke patients, patients on the neurosurgery service, orthopedic patients, where the incidence of DVT would be much higher, you would have a higher event rate and a more robust study. That leads to my question: What population are you going to study next with a head-to-head comparison?

Ms Proctor. We included all patients admitted to the university adult hospital who were assigned by their physician to have mechanical prophylaxis, and so it included all of the groups that you reflected: trauma, orthopedic surgery, and medical patients. There were about 75% surgical and 25% medical patients among those assigned to use the devices.

Dr Thomas Brothers (Mt Pleasant, SC). Certainly any time you make the statement that there is no difference between groups, there is the strong chance of a type II error, especially when there is such a low event rate. I would caution you about some of the findings, about no difference in terms of knee-high versus thigh-high devices.

There is a large proportion of patients who are at risk for DVT, namely, the trauma patients, especially those with orthopedic trauma, who, because of their orthopedic injury, cannot use the typical type of sequential pump, only use a foot pump. I wondered if you have any plans of evaluating some of the foot pump devices.

Ms Proctor. The foot pump devices were included in this study; however, none of the physicians ordered those devices to be used on any patient during that 5-month period. At earlier points in time the trauma unit had used a foot pump but has since come to rely on the pharmacologic prophylaxis when possible.